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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,200	04/09/2004	David Lentz	760-129 DIV/CIP/CON II	2373
23869	7590	11/15/2005	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			GHERBI, SUZETTE JAIME J	
			ART UNIT	PAPER NUMBER

3738

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/822,200

Applicant(s)

LENTZ ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Gor-tex definition.

### DETAILED ACTION

1. Applicant's RCE and amendment dated 10/17/05 have been received in application serial number 10/822,220. All comments have been taken into considerations.

#### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 29-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanzer 4,619,641 in view of Parsons et al. 6,521,284 and further in view of Tu et al. 4,816,339. Shanzer discloses the invention as claimed comprising: a first tubular (11) structure having a first thickness/porosity; and a second tubular (13) structure having a second thickness/porosity wherein the tubular structure is disposed externally about the first tubular structure and a re-sealable layer (15) made of silicone (a polymer) which is interposed between the first and second tubular structures for the purpose chronic hemodialysis access (col. 1, lines 9-18, col. 2, line 65). While Shanzer does disclose a **GOR-TEX** material (col. 2, lines 53-54), Shanzer does not specifically state the term **ePTFE**, internodal distance or adherence or a flowable material. It is obvious to one

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having ordinary skill in the art that Gor-tex materials are typically based on expanded PTFE and used in a variety of applications (see attached document called "Gore-Tex" [www.gortex.com](http://www.gortex.com)).

5. Parsons et al. teaches grafts (see figures 1-4) with self-sealing properties (col. 10, lines 64-67 to col. 11, lines 1-51), which utilize ePTFE (col. 9, lines 19-21); a hydrogel that contains water (which equates to the flowable gel, see col. 6, lines 30-33); and wherein the self-sealing material is disposed within a cavity such that the cross-linkable material is adjacent to layers (22) (see col. 5, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a self-sealing flowable layer that adheres to the first and second layers because the flowable gels are known to deform elastically and then recover to their original form which would aid in the production of attaching the gel to the layers of the graft.

Shazner and Parsons et al. have been disclosed however Shazner does not *specifically state* the term internodal distance. It is well known to those having skill in the art that internodal distance is synonymous with porosity. Nevertheless Tu et al. specifically states that layer grafts made having first and second structures/layers have first and second internodal distances that are different from each other (see col. 2, lines 36-64).

Therefore it would be obvious to vary the internodal distances of Shazner because both devices are grafts that can be utilized as vascular access devices made from the same materials.


***Response to Arguments***

6. Applicant's arguments filed 10/17/05 have been fully considered but they are not persuasive. Applicant has amended the claims from porosity to internodal distance and continues to argue that Shazner does not have a first and second structure with different internodal distances. This allegation has been addressed above with the 103 combinations of Shazner, Parsons, and Tu et al. Tu further illustrates that vascular access grafts may be layered and have different internodal distances/porosities in each structure. To further reiterate that Gortex is ePTFE a definition has been supplied.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Suzette J-J Gherbi  
07 November 2005